510(k) Summary

MAR 15 2007

Introduction

This summary is intended to comply with requirements of the SMDA and 21CFR§807.92. FDA may make this summary available to the public within 30 days following a finding of substantial equivalence.

510(k) Applicant & Holder

Unisensor AG
Bahnstrasse 12a
Attikon CH-8544
Switzerland

510(k) Correspondent

Robert N. Clark, President and Senior Consultant
Medical Device Regulatory Advisors
13605 West 7th Ave., Golden, CO USA
Tel: 303-234-9412 / Fax: 303-234-9413

Date Prepared

July 19, 2006

Proprietary Name of Device

UniTip High Resolution GI Catheter

Classification Name

Gastrointestinal motility monitoring system

510(k) Classification

Class II FFX

Device Description and Intended Use

The Unisensor UniTip Gastrointestinal Pressure Sensor Catheter product line consists of multiple ultra-miniature solid-state pressure sensors, located at the distal end of a gastrointestinal catheter. pH sensors, silicon rubber sleeves, lumen, and conductive impedance rings, may also be included. There are scanning electronics for multiplexing the sensor signals, and an electrical connection located at the proximal end to carry the sensor element signals to an external gastrointestinal motility recording equipment. The UniTip GI catheters are produced in various lengths and catheter sizes.

This modification consists of increasing the maximum number of pressure sensor elements to 40. The closer proximity of the pressure sensor elements to each other allows for high-resolution

mapping of pressures within the organs of the human gastrointestinal tract. This modification also increases the maximum number of pH sensors to 7, and the maximum number of impedence rings to 14.

Predicate Devices

Unisensor AG, UniTip Pressure Sensor Catheter K003580

Sierra Scientific Instruments, Inc., Motility Visualization System K031169

Biocompatibility

The requirements of the following standards have been used in part to establish substantial equivalence:

EN 30993-1/ISO 10993-1 "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing"

The company did not conduct, nor depend on, clinical studies in order to establish substantial equivalence.

Risk Management

This device has been designed to either completely eliminate or mitigate known health hazards associated with the use of the device. Health hazard risk reduction has been accomplished by rigorous application of a risk management program.

Unisensor AG believes that the UniTip High Resolution GI Catheter is safe and effective when used as instructed by knowledgeable and trained personnel, and is substantially equivalent to the legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

MAR 15 2007

Unisensor AG
c/o Mr. Robert N. Clark
Medical Device Regulatory Advisors
13605 West 7th Avenue
GOLDEN CO 80401

Re: K062222
Trade/Device Name: Unitip High Resolution Catheter
Regulation Number: 21 CFR §876.1725
Regulation Name: Gastrointestinal motility monitoring system
Regulatory Class: II
Product Code: FFX
Dated: February 22, 2007
Received: February 26, 2007

Dear Mr. Clark:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: UniTip High Resolution Catheter

Indications for Use:

The catheter probe is used to obtain a high resolution mapping of peristaltic activity or pressure within the organs of the gastrointestinal tract, and to allow storage of the corresponding data.

The device is manufactured in the basic model variations listed below:

1. High Resolution Gastrointestinal Catheter with up to 40 pressure sensors:

   This model variation is intended for simple direct esophageal pressure, either at, above, or below the specific site of interest. Pressure information is provided at multiple sensor sites. Pressures may be measured continuously, at rest, or dynamically.

2. Gastrointestinal catheter, with pH sensors:

   This model variation is the same as the High Resolution Gastrointestinal (GI) catheter described above, except that this model variation includes up to 7 pH sensors. PH probes are added to allow measurements of pH in the stomach and/or esophagus.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lyngson

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K062222

3. Gastrointestinal catheter, with sleeve:

   This model variation is the same as the High Resolution Gastrointestinal (GI) catheter described above, except one or more of the pressure sensor sites will include a sleeve. The sleeve is added to broaden the pressure sensitive zone for the sensor site, and reduce positioning sensitivity.

4. Gastrointestinal catheter, with impedance rings:

   This model variation is the same as the High Resolution Gastrointestinal (GI) catheter described above, except it includes up to 14 conductive rings for impedance studies.

5. Gastrointestinal catheter, with lumen

   This model variation is the same as the High Resolution Gastrointestinal (GI) catheter described above, except it includes a lumen.